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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,758

09/23/2005

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58049-00019

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05/19/2008

EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

05/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application Status

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/30/08 has been entered.

In response to the Final Office Action dated 10/30/2007, applicants' filed an RCE received on 04/30/08 is acknowledged. In said RCE, applicants' amended claims 1, 2, 5, 7 and 13, cancelled claims 3, 14 and 16 and added new claims 21-23.

Claims 1, 2, 5-7, 9, 13, 15 and 20-23 are pending and are now under consideration in the instant Office Action.

Objections and rejections not reiterated from previous action are hereby withdrawn.

Withdrawn-Claim Rejections 35 USC § 102

Previous rejection of claims 1, 2, 5, 9, 14 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al., (2002) when given the broadest interpretation is being withdrawn due to amendments to the claims.

New Matter-Claim Rejections 35 USC § 112

Claims 5 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 5 and 20 are rejected because an isolated or recombinant protein of SEQ ID NO: 7 and having phytase activity wherein the specific activity of the protein to phytate is at

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least 3,000 units/mg is new matter. The scope of polypeptide of SEQ ID NO: 7 as claimed was not contemplated in the specification as originally filed. The specification has support only for a mature polypeptide lacking the signal sequence (amino acid sequences 1-22) having phytase activity i. e., as the active phytase comprises amino acid residues 23-433 of SEQ ID NO: 7 (411 amino acids; page 9, lines 9-15; examples 3-4, pages 20-30). The protein of claims 5 and 13 wherein the specific activity of the protein to phytate is at least 3,000 units/mg as in original claims 5 and 13 has a different scope than the protein (pre-protein, unprocessed and having the N-terminal signal peptide of amino acid residues 1-22 of SEQ ID NO: 7) of amended claims 5 and 13 now claimed.

Claim Rejections: 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 5, 9, 13 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for an isolated recombinant polypeptide comprising the amino acid residues 23-433 of SEQ ID NO: 7 and encoded by a polynucleotide sequence of SEQ ID NO: 6 having phytase activity, wherein the specific activity of the said mature protein (lacking signal sequence, amino acid residues 1-22) to phytate is at least 3,000 units/mg and to a feed additive comprising said polypeptide as an effective ingredient, does not reasonably provide enablement for an isolated recombinant polypeptide consisting of the amino acid sequence of SEQ ID NO: 7 i.e., unprocessed pre-protein and encoded by a polynucleotide having the nucleotide sequence of SEQ ID NO: 6 and having phytase activity, wherein the specific activity

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of the said pre-protein (having the signal sequence) to phytate is at least 3,000 units/mg and to a feed additive comprising said polypeptide as an effective ingredient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to an isolated recombinant polypeptide consisting of the amino acid sequence of SEQ ID NO: 7 i.e., unprocessed pre-protein and encoded by a polynucleotide having the nucleotide sequence of SEQ ID NO: 6 and having phytase activity, wherein the specific activity of the said pre-protein (having the signal sequence) to phytate is at least 3,000 units/mg and to a feed additive comprising said polypeptide as an effective ingredient as encompassed by the claims. However, in this case the disclosure is limited to an isolated recombinant polypeptide comprising the amino acid residues 23-433 of SEQ ID NO: 7 and encoded by a polynucleotide sequence of SEQ ID NO: 6 having phytase activity, wherein the specific activity of the said mature protein (lacking signal sequence, amino acid residues 1-22) to phytate is at least 3,000 units/mg and to a feed additive comprising said polypeptide as an effective ingredient. It would require undue experimentation of the skilled artisan use the claimed polypeptides and encoding

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polynucleotides i.e., recombinant polypeptide consisting of the amino acid sequence of SEQ ID NO: 7, the unprocessed pre-protein and encoded by a polynucleotide having the nucleotide sequence of SEQ ID NO: 6. The specification is limited to teaching the use of an isolated recombinant polypeptide comprising the amino acid residues 23-433 of SEQ ID NO: 7 and encoded by a polynucleotide sequence of SEQ ID NO: 6 having phytase activity, wherein the specific activity of the said mature protein (lacking signal sequence, amino acid residues 1-22) to phytate is at least 3,000 units/mg and to a feed additive comprising said polypeptide as an effective ingredient, but provides no guidance with regard to the use of recombinant polypeptide consisting of the amino acid sequence of SEQ ID NO: 7, the unprocessed pre-protein and encoded by a polynucleotide having the nucleotide sequence of SEQ ID NO: 6. In view of the great breadth of the claims, amount of experimentation required to make and use the claimed polypeptides and encoding polynucleotide and, the lack of guidance, working examples, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim. Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the use of recombinant polypeptide consisting of the amino acid sequence of SEQ ID NO: 7, the unprocessed pre-protein and encoded by a polynucleotide having the nucleotide sequence of SEQ ID NO: 6. The scope of claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA)). Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily, and

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improperly, extensive and undue. See *In re Wands* 858 F. 2d 731, 8 USPQ 2nd 1400 (Fed. Cir., 1988).

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

1. Claims 5 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement/New-matter.
2. Claims 5, 9, 13 and 20 are rejected under 35 U.S.C. 112, first paragraph for enablement.
3. Claims 1, 2, 6, 7, 15 and 21-23 are allowed.

Allowable Subject Matter/Conclusion

Claims 1, 2, 6, 7, 15 and 21-23 are allowed. However, Claims 5, 9, 13 and 20 are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this

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final action.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
Art Unit 1652
May 14, 2008.

/Rebecca E. Prouty/
Primary Examiner,
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